



Technical Trade Report

Updates on Key Trade Policy Issues Affecting APHIS

October 1999
***** Special Edition *****

CONTENTS

- **Executive Summary**
- **Status of Global PRA Standards**
- **Global Training Needs in PRA**
- **Implications of Recent WTO Disputes for PRA**
- **Summary and Conclusions**

Technical Trade Report is on the Trade Support Team Home Page
<<http://www.aphis.usda.gov/is.tst>>

SPECIAL EDITION OF THE TECHNICAL TRADE REPORT

October 1999

State of Pest Risk Analysis in the World

SEMINAR PROCEEDINGS

July 23, 1999

This report summarizes the discussions and some of the key issues which emerged at a July 23, 1999 seminar on pest risk analysis (PRA). Discussions focused on the status of global PRA standards, APHIS role in providing PRA training to other countries, and implications of recent WTO disputes for PRA.

Executive Summary

The World Trade Organization (WTO) Agreement on Sanitary and Phytosanitary Measures (i.e., SPS Agreement) has been in force 5 years. The SPS Agreement includes the requirement that members base SPS measures on scientific pest risk assessments (PRAs). Developed countries had to meet this obligation since the Agreement was first implemented. In 2000, least developed countries will also assume the obligation to base SPS measures on scientific risk assessments. Many of these less developed countries are struggling to acquire basic PRA capabilities. Long term challenges include how to level the playing field among countries as it relates to conducting PRAs.

There have been oft repeated concerns that international PRA training activities siphon away staff resources from accomplishing APHIS in-house PRA work. However, many agree that APHIS participation and/or leadership in such training events provides strategic opportunities to: 1) promote U.S. concepts among developing countries who are in the process of trying to learn and adopt PRA processes; 2) demonstrate the use of science-based approaches for managing risk and promote the feasibility of alternative risk mitigation measures besides post harvest treatments as means to ensure safe trade. This ostensibly supports U.S. exports that rely on other risk management systems besides fumigation; and, 3) strengthen regulatory infrastructure in foreign countries, which enhances regional and global pest and disease conditions. There have been three SPS-related cases brought to the WTO's Dispute Settlement Body.

Decisions in these three SPS disputes indicate that countries must ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations. The

results of the three cases have not clarified the rules surrounding the appropriate level of protection. Nor has the WTO panel process provided guidance on how to conduct a PRA. It has clarified that there are tools available for doing risk assessments, and that a risk assessment must be performed.

Some important perspectives that emerged from the July 23 workshop include: 1) the current approach for providing PRA training appears fragmented and piecemeal; 2) APHIS risk assessment staffs need to reach agreement on core elements in risk assessment, particularly methodologies, to be more effective in promoting a coherent U.S. approach with foreign counterparts; 3) APHIS needs better management, centralization, and organization of PRA resources within the Agency; 4) there is a need for greater consistency in content of PRA training from one workshop to another and across APHIS; 5) APHIS needs to identify a lead within the Agency that will be accountable for promoting consistency in content of training, priority setting, appropriate funding, leveraging and coordinating of resources, and delivery.

Introduction

A seminar on Pest Risk Analysis (PRA), open to all APHIS and USDA personnel, was held on July 23, 1999, in APHIS Riverdale facilities. Objectives of the seminar were to discuss:

- status of current and future international PRA standards;
- global training needs in PRA and APHIS role in such training; and,
- implications of recent rulings from disputes adjudicated under the World Trade Organization (WTO) for PRA.

The purpose of the seminar was to update staffs on these topics and to identify organizational, strategic, and policy issues surrounding these topics. For example, there have been oft-repeated concerns that international PRA training activity is siphoning away staff resources from accomplishing APHIS in-house PRA work. The seminar provided an opportunity for an open discussion among agency staffs on APHIS strategic interests in participating in PRA training events.

A representative from the Secretariat of the International Plant Protection Convention (IPPC), Robert Griffin, was present in an unofficial capacity to discuss the status of international PRA standards. Mr. Griffin also provided perspectives regarding PRA capabilities in different regions in the world. A panel consisting of APHIS risk assessment experts discussed their experiences and views in delivering PRA training to foreign officials. Another panel discussed the outcome of recent World Trade Organization (WTO) disputes and how the WTO dispute panels have interpreted members obligation to base sanitary and phytosanitary (SPS) measures on risk assessment.

Special thanks go to the panelists including Ed Podleckis (APHIS, Plant Protection and Quarantine), Ed Miller (APHIS, Policy and Program Development), Gary Cave (APHIS, Plant Protection and Quarantine), Peter Bonner (USDA, Office of General Counsel), Craig Fedchock (APHIS, Trade Support Team), Bob Griffin (IPPC Secretariat), and Mary Lisa Madell (Trade Support Team). Nearly 60 people attended this seminar. A list of participants is attached.

Status of Global PRA Standards

This was the first session in the July 23 seminar. The objective of this session was to heighten awareness of current and future international standards which will affect the conduct of PRAs. Mr. Griffin led the discussion by noting that the WTO SPS Agreement has been in force 5 years. In 2000, least developed and developing countries will assume all the obligations contained in this agreement, including the obligation to base SPS measures on scientific risk assessments. Mr. Griffin noted that many of these less developed countries are struggling to acquire basic PRA skills and information.

Griffin indicated that a PRA standard currently exists under the IPPC. This standard, adopted in 1995, is referred to as Guidelines for Pest Risk Analysis (International Standard for Phytosanitary Measures (ISPM) No. 2). Efforts are currently underway to develop a more detailed PRA guidelines for quarantine pests. Griffin indicated that these draft guidelines will be distributed to member countries in October 1999 for country review. The draft standard should be ready for adoption by the Interim Commission on Phytosanitary Measures (ICPM -- the governing body of the IPPC) in 2000.

PRA guidelines will also be needed for the new category of pest described in the revised Convention as Regulated Non-Quarantine Pest (RNQP). The revised Convention defines an RNQP as a non-quarantine pest whose presence in plants for planting affects the intended use of those plants with an economically unacceptable impact and which is therefore regulated within the territory of the importing contracting party. * *According to Mr. Griffin, guidelines for assessing RNQPs are likely to require greater consideration of the economic consequences than is the case in assessments of quarantine pests. Griffin noted that this emphasis on economic factors, related to RNQP assessments, makes it an area of potential abuse by countries.

Mr. Griffin noted the inconsistency of terms used in the SPS Agreement, IPPC, Office of International Epizootics (OIE), and Codex Alimentarius. This has caused some confusion among regulatory officials of different countries, particularly developing nations, who are trying to understand and adopt PRA processes.

The immediate challenge for countries is to harmonize risk assessment terms and methodologies, not only within the plant quarantine field, but also between IPPC, OIE, and Codex so governments have a common understanding of basic risk assessment terms and concepts regardless of discipline. Other challenges include: addressing and clarifying concepts such as the precautionary principle, environmental protection, and consistency

in the level of protection; and strengthening the information exchange between countries to assure access to the best data for PRAs.

Long term challenges include how to level the playing field among countries as it relates to conducting PRAs, particularly countries' access to data. Also, a number of countries utilize and promote the use of process outlines (i.e., checklists/guideline approach for assessing pest status and risk). Mr. Griffin indicated the need to harmonize these process outlines. Furthermore, the criteria for assessing economic impact (i.e., determining consequences) also needs to be refined and harmonized. Finally, more PRAs need to be done with fewer resources

** The traditional focus of the Convention was on quarantine pests (i.e., pests that do not exist in the importing country or are present but are limited and are under official control). The revised Convention expands this scope to cover regulated non quarantine pests. These are pests which are present in the importing country and are regulated to keep their population at specified levels. Disciplines are established in the revised Convention which require that phytosanitary requirements taken against RNQPs be transparent, technically justified, and no more restrictive than measures imposed on the same pest if present domestically.*

According to Mr. Griffin, agriculture-focused PRAs can be extended to assessments of pests of the environment and other risk-based decision making for biological hazards. Griffin shared his concerns with the recently adopted Convention on Biological Diversity, recent negotiations on a biosafety protocol, and the recent U.S. Executive Order on Invasive Species. Griffin noted that these initiatives appeared to ignore internationally accepted PRA approaches and concepts. Last, Griffin noted that the management of rapidly expanding information exchange is presenting a major challenge for organizations such as FAO and the IPPC Secretariat.

Global Training Needs in PRA

This was the second session in the July 23 seminar. The goal of this session was to gain insight into which countries/regions are deficient in PRA capabilities, examples of recent technical assistance efforts in the PRA area, and the types of training that appears to be effective.

Global Situation --

Perspectives of the IPPC Secretariat

The following were perspectives provided by Mr. Griffin.

- Australia, Canada, New Zealand, the EU, and the U.S. have been the most active in offering and conducting PRA training internationally. The EU, for example, has been active in providing PRA assistance to East African countries.

- Generally, countries in Africa are stabilizing their trade policies and seeking to acquire the information necessary to make their regulatory regimes consistent with their WTO obligations. As a whole, Africa is making progress in obtaining some basic PRA information through regional PRA workshops. Nonetheless, compared to other regions, Africa and the Near East are at the least advanced in terms of PRA capabilities.
- Japan and China are the most advanced in the Asia region in terms of their PRA capabilities. China remains closed and rigid in its regulatory approach, but has been watching the rest of the world and is interested in the evolving PRA science.
- The Caribbean countries are generally more interested in tourism than agricultural trade. As a result, few resources have been invested in developing their quarantine infrastructure and promoting an understanding of their SPS obligations.
- While Central America has an active regional plant protection organization (OIRSA), this organization has not kept pace with developments in PRA nor made a concerted effort to promote PRA. It continues to direct its resources to acquisition and use of traditional quarantine treatments as a means to manage pest risk rather than develop risk assessment capabilities necessary to evaluate pest risk potential and employ alternative risk management strategies.
- South American cone countries (COSAVE) are the strongest group of countries in the South American region with regard to developing and implementing PRA processes and standards. The other countries of South America remain weak in terms of PRA capabilities, but remain open to training and other technical assistance programs that may be available.
- Europe is fractured in terms of their PRA policies and positions. The Community, EPPO, and individual member states each have distinct agendas and personalities which have led to less than uniform approach to PRA.

APHIS Perspectives

PRA experts from APHIS discussed several workshops they have helped design and implement internationally. These training efforts took place in Poland, South Africa, Brazil, and Fiji. With the exception of the workshop held in Fiji, funding was provided through the Technical Issues Resolution Fund, administered by FAS.

The workshops in Poland, Brazil and Fiji had regional participation: representatives from throughout Eastern Europe participated in the workshop in Poland, representatives from Paraguay, Argentina, Chile, Uruguay, and Colombia joined a large number of Brazilian participants in the workshop held there, and representatives from Fiji, the Federated States of Micronesia, Tonga, and Vanuatu participated in the workshop in Fiji. Regional coverage was identified as an important way to leverage APHIS resources in PRA training.

The workshops provided different types of training -- some included detailed instruction in conducting PRAs, while some were more introductory in nature. The type of training that was provided was influenced by the level of expertise of the participants, the target audience for the training, and the objectives of the workshop. For example, in those workshops where participants were risk assessors or risk managers, the mechanics of conducting a PRA were covered. The agenda for the workshop in Poland also included biotechnology, an important issue in Central and Eastern Europe. However, all workshops emphasized both the obligations under the WTO SPS Agreement and the role of the IPPC in the development of international standards. The APHIS PRA experts identified several factors that contributed to the success of the workshops. These included using case studies and breakout sessions, ensuring that the presentations were clear enough to allow good translation or for nonnative English speakers to understand, ensuring that participants and presenters were working with common definitions of technical terms, providing extensive take-home materials to reinforce the concepts presented, and, where possible, including non-APHIS presenters, for example, from FAO or a regional organization.

Implications of Recent WTO Disputes for PRA

This was the third session in the July 23 seminar. The objective of this session was to discuss the implications and lessons learned from recent WTO dispute panel rulings for PRA. The session focused on the jurisprudence regarding PRAs developed in three recent dispute settlement cases involving the SPS Agreement.

WTO Dispute Settlement Process

The dispute settlement process under the WTO is significantly improved from that which existed under the General Agreement on Tariffs and Trade (GATT). Previously, countries that disagreed with a GATT decision could simply block it. When the dispute settlement mechanism of the WTO was created, a timeline for the settlement of disputes was put into place, with a requirement for countries to take actions within a defined period of time should they be on the losing end of a dispute. Of greatest significance is that countries can no longer block decisions made by the Dispute Settlement Body.

While these improvements are significant, the end result of a dispute taken to the WTO may not provide the desired results. A good example of this is the EU beef hormone case. While the United States was seeking to open the European market to exports of U.S. beef, and the WTO Dispute Settlement Body (DSB) agreed with the United States that the EU's regulations were contrary to the EU's obligations, U.S. beef is still not entering the EU. This is because the EU has refused to change its regulations, with the result that the DSB has said that the United States can increase its tariffs on EU exports to the United States to an equivalent dollar amount of lost sales of U.S. beef.

There have been three SPS-related cases brought to the WTO's Dispute Settlement Body. Two of these involved the United States as a first party. Interestingly, each one deals with

one of the three areas of the SPS Agreement (human, animal, and plant health). In the beef hormone case, the EU banned U.S. beef for human health reasons, supposedly based on food safety concerns related to hormones.

The Canadians brought a case against Australia dealing with restrictions against Canadian salmon for animal health reasons. The United States and Japan contested a plant health case in which Japan argued that the variety of an apple, nectarine, cherry or walnut mattered when considering the efficacy of a methyl bromide treatment to control codling moth (i.e., the varietal case). In all three cases, the defendants (the EU, Australia, and Japan) lost because they could not scientifically defend their measures.

Generally, the panels, formed under the DSB to review the case, are not made up of scientists. There is usually little or no knowledge about the scientific arguments being put forward by the parties. Rather, panels, consisting of legal or trade specialists, go directly to the text of the SPS Agreement to make determinations on the legality of an SPS measure subject to dispute. Panels are not precluded from seeking scientific advice from experts (agreed by the parties), which may be necessary to gain an understanding of the technical issues. In fact, in each of the three cases above, the panelists relied on panels of technical experts to guide them in their understanding of technical issues.

Lessons Learned

- At this point, it appears that only serious cases with major economic consequences make it to the WTO. This is due to technical, legal, and other staff resources required to prepare and execute the cases.
- Decisions in the three SPS disputes conducted thus far provide some answers to the question of what it means to base a measure on risk assessment. First, it is clear that a risk assessment must be based on sufficient scientific evidence. Second, pest risk assessments (i.e., phytosanitary risks) must adhere to the minimum requirements set forth in the IPPC pest risk analysis guidelines (per SPS Agreement, Article 5.1: Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal, or plant life or health, *taking into account risk assessment techniques developed by the relevant international organizations.*)
- The risk assessment must identify the disease or pest of concern. Beyond that, potential economic and risk evaluations must be conducted, including an assessment of the mitigated risk (i.e., after mitigation measures have been taken by the exporting country).
- The Panel in any SPS-related must be shown that a country has conducted a risk assessment which addresses both the mitigated and unmitigated risk, consistent with scientific principles.
- The risk assessment must be sufficient to justify the measure to meet the level of protection established by the importing country. If the measure indicates a higher level of

protection is needed than that provided for by international standards, the country needs the scientific evidence of a PRA to justify the higher level.

- A country must not apply a restriction to one commodity for a perceived risk while allowing another commodity of equal risk from the same or different country to have access. Australia's ban on Canadian salmon while permitting entry from Canada of live fin fish with higher risk is an example for this point. Another is the EU's restriction on beef treated with hormones while allowing the marketing of hormone-treated pork.
- The ruling in the Japan varietal case demonstrates the obligation of member countries to publish their SPS requirements in such a way that other members can understand what they must do to meet a given pest or disease concern. In the varietal case, Japan informed the DSB panel that information on its varietal testing requirement was available to any country that *requested* the information. However, the panel ruling indicates that a country must publish its measures with which compliance is required irrespective of whether the country considers it a legal obligation.
- The WTO will not dictate *how* to conduct a PRA, but the dispute settlement process has emphasized that a risk assessment must be performed.
- The recent SPS disputes have not answered the question of how much evidence is necessary to justify an SPS measure. The panels have confirmed that if a country believes that there is a particular pest or disease risk, it may adopt a provisional measure, prior to conducting a PRA. However, should a provisional measure be adopted, that country must make a good faith effort to seek additional scientific information to support or modify its measure accordingly. In addition, provisional measures must be reviewed within a reasonable period of time. To a large extent, Japan lost its case by not trying to develop information to refute or confirm its theory on varietal testing.

Summary and Conclusions

- Significant differences exist between PRA approaches used by the EU and the United States. APHIS participation and/or leadership in international PRA training helps ensure that U.S. concepts are promoted and considered by developing countries who are in the process of trying to learn and adopt PRA processes.
- PRA training in the past has been driven by: 1) executive level commitments made to another country to provide technical assistance through training; 2) need to fulfill commitments made in the field; 3) perceived need to promote understanding and broad implementation of the SPS Agreement; 4) pressure to respond to training agendas of other USDA agencies and external organizations; and, 5) pressure to accomplish a specific bilateral SPS trade issue through training.

- Several participants stressed that PRA training was an essential activity for implementing the SPS Agreement among countries. Many agreed that there are strategic benefits for engaging in PRA training, including:

- opportunity to demonstrate the use of science-based approaches for managing risk and promote the feasibility of alternative risk mitigation measures besides post harvest treatments as means to ensure safe trade. This ostensibly supports U.S. exports that rely on other risk management systems besides fumigation;

- opportunity for APHIS risk assessors to obtain international perspectives on risk analysis;

- opportunity for APHIS technical staffs to network and strengthen relations among risk assessment practitioners and foreign regulatory officials;

- opportunity to promote U.S. concepts and increase U.S. influence in a particular region; and,

- opportunity to strengthen regulatory infrastructure in foreign countries, which enhances regional and global pest and disease conditions.

- Attention was turned to the existence of PRA expert lists developed by NAPPO and shared with the WTO. The listing contains contact information for experts in the NAPPO region. Perhaps this listing could be the basis for an expanded list of experts from other regions. The EU has developed a similar PRA experts list. This could serve as a resource for officials in developing countries. It could also lead to more calls and requests for assistance.

- Policy issues and questions that emerged from the seminar include:

- The question is not whether international PRA training is necessary, but rather who in APHIS should provide it;

- The current approach for providing such training appears to be fragmented and piecemeal;

- A more coordinated effort should be taken to leverage resources outside of APHIS for PRA training activities (e.g., FAS and AID);

- APHIS risk assessment staffs need to reach agreement on core elements in risk assessment, particularly methodologies, in order to be more effective in promoting a coherent U.S. approach with foreign counterparts;

- APHIS needs better management, centralization, and organization of PRA resources within the Agency;

- It was suggested that APHIS Professional Development Center (PDC) could operate as a hub for PRA training;
- We need greater consistency in content of PRA training from one workshop to another and across APHIS;
- We need to examine costs and who pays; and,
- We need to identify a lead within APHIS that will be accountable for promoting consistency in content of training, priority setting, appropriate funding, leveraging and coordinating of resources, and delivery.